UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW MEXICO

JON WHITSITT, Plaintiff, v. MECTA CORPORATION; and DOES 1-10, Defendant(s).	Case No.: **COMPLAINT FOR DAMAGES** **(Jury Trial Demanded)**

COMPLAINT

Plaintiff JON WHITSITT, by and through his counsel, brings this Complaint against Defendant MECTA CORPORATION, and alleges as follows:

NATURE OF THE ACTION

1. This common-law products liability, negligence and fraud action arises out of serious and debilitating cognitive injuries that Plaintiff, JON WHITSITT ("Plaintiff" or "Mr. Whitsitt") sustained as a result of undergoing multiple rounds of electroconvulsive shock treatment with a device manufactured and/or distributed by defendant, MECTA CORPORATION ("Defendant" or "MECTA").

2. The injuries Mr. Whitsitt sustained as a result of MECTA's shock treatment device, include but are not limited to, brain damage, neurocognitive injuries, severe permanent memory loss, significant decline in his ability to learn and recall information, a disruption and decline in his ability to encode new information, diminished quality of life, additional physical, physiological, psychological, and emotional injuries and harms, and lost wages and earning capacity.

3. Plaintiff alleges that MECTA negligently and intentionally concealed and failed to adequately disclose and warn about risks, including but not limited to, brain damage and permanent neurocognitive injuries associated with its shock treatment device. In addition to concealing risks, MECTA intentionally, recklessly, and overtly misrepresented the safety and

efficacy of the shock therapy device.

PARTIES

4. Plaintiff, JON WHITSITT, is an adult and a resident and citizen of the state of New Mexico.

5. At all relevant times, MECTA is and was a corporation formed and existing under the laws of the State of Oregon with its principal place of business at 19799 SW 95th Place B, Tualatin, Oregon.

6. MECTA is the manufacturer, labeler, promoter, and distributor of the "Thymatron" Electroconvulsive Therapy ("ECT") shock device. An ECT shock device is a device used for treating severe psychiatric disturbances by inducing in the patient a major motor seizure through the application of a brief intense electrical current to the patient's head. An ECT shock device, in lay terms, is used to administer "shock treatment."

7. Upon information and belief, MECTA regularly conducts and transacts business in New Mexico and has sold the Thymatron ECT devices to multiple hospitals and medical facilities in New Mexico, including but not limited to, the medical facility where Plaintiff received his ECT treatment, and MECTA has generated revenue from sales within New Mexico. This Court has personal jurisdiction over MECTA because it has sufficient minimum contacts in New Mexico to render the exercise of jurisdiction by this Court proper.

8. The identities, capacity, and or/nature of involvement of the Defendants sued as DOES 1-10 are presently unknown to Plaintiff who therefore sues these Defendants by fictitious names. Plaintiff is informed, believes, and thereupon alleges that DOES 1 through 10 include business entities and or individuals who were involved in the design, manufacturing, marketing, promotion, distribution, or sale of ECT devices or individual components of ECT devices, and is inclusive of the principles, agent contractors, and employees of said DOES 1 through 10, all of whom were acting within the course and scope of their authority as such agents and employees.

\\

\\

JURISDICTION AND VENUE

9. Plaintiff incorporates by reference all prior paragraphs of this Complaint as if fully set forth herein.

10. Plaintiff Jon Whitsitt is a resident and citizen of the State of New Mexico.

11. This Court has subject matter jurisdiction over the parties pursuant to 28 U.S.C. §1332(a) because Plaintiff and Defendant are citizens of different states and the amount in controversy exceeds $75,000, exclusive of interest and costs.

12. Venue is proper in this Court pursuant to 28 U.S.C. § 1391(b)(2), in that a substantial portion of the events and omissions giving rise to this lawsuit occurred in this District and the Court has personal jurisdiction over each of the parties as alleged throughout this Complaint.

GENERAL ALLEGATIONS

A. Brief History of the Discovery of ECT

13. Electroconvulsive therapy ("ECT") is the practice of inducing grand mal motor seizure through application of electricity to the brain. In the late 1930's after observing slaughterhouses apply electricity to pigs to render them manageable for slaughter, Ugo Cerletti and Lucino Bini, two scientists at the University of Rome thought that electricity could be used to treat schizophrenia. Scientists at the time theorized (incorrectly) that *seizures* could potentially cure or decrease the symptoms of schizophrenia and thus were considering using electricity to induce grand mal seizure with the hopes of curing schizophrenia.

14. Cerletti and Bini began to test their theory by applying electricity to dogs and it was noted by Bini that the majority of the dogs died during the experiment.

15. In April 1938, after having sacrificed sufficient dogs, Cerletti and Bini applied ECT to the first human patient. A 40-year old Italian man who had been found wandering the train station in Rome and speaking gibberish was brought to the University of Rome and had 70 volts of electricity applied to his temple by Cerletti. It has been reported that, while the scientists were deliberating whether they should apply a second higher voltage, the patient pleaded "*Non*

una seconda! Mortifera!" ("not again it will kill me!"). Seeing success that the man was speaking lucidly as opposed to his initial gibberish, Cerletti applied a second and higher voltage (110 volts) of electricity. The scientists reported that, after the application of the electricity, the patient became more lucid and was able to speak coherently. The patient was administered approximately a dozen more sessions of ECT and was eventually discharged but subsequently lost to follow-up.

16. In May 1938, Cerletti publicly presented his results on the use of ECT on this patient at the Medical Academy of Rome. Shortly thereafter and starting in the early 1940s, ECT began to gain acceptance for the purported treatment of schizophrenia (and eventually other psychiatric ailments) across Europe and in the United States.

17. It may come as a surprise to some, but ECT shock treatment is still presently prescribed in the United States for various psychological disorders including, but not limited to, depression, bipolar disorder, schizophrenia and catatonia and is used on patients of all ages, including children and the elderly. In an effort to veil the image of patients jolting, jarring and convulsing during the procedure, patients are now placed under anesthesia and muscle relaxants during the procedure, but as outlined herein, while these may mask the image of overt convulsions, the devastating permanent side-effects of ECT on the body and the brain remain the same, and in some cases, exacerbated.

B. Regulatory History of ECT

18. Prior to 1976, medical devices could be marketed without review by the U.S. Food and Drug Administration (FDA). Spurred by the increased technological complexity of devices and mounting disclosures of shortcomings involving pacemakers, intrauterine devices, and intraocular lenses, Congress enacted the comprehensive Medical Device Amendments of 1976 to the Federal Food, Drug, and Cosmetic Act. The primary purpose of the amendments was to ensure that new devices were safe and effective before they were marketed." Kessler DA et al., *The Federal Regulation of Medical Devices*, THE NEW ENGLAND JOURNAL OF MEDICINE, August 8, 1987.

19. The Federal Food, Drug, and Cosmetic Act (hereinafter, the "Act") (21 U.S.C. 301 *et seq.*), as amended by the Medical Device Amendments of 1976 (the "1976 amendments") (Public Law 94-295), the Safe Medical Devices Act of 1990 (the "SMDA") (Public Law 101-629), the Food and Drug Administration Modernization Act of 1997 ("FDAMA") (Public Law 105-115), the Medical Device User Fee and Modernization Act ("MDUFA") (Public Law 107-250) and the medical device provisions of the Food and Drug Administration Amendments Act of 2007 ("FDAAA") (Public Law 110-85), along with the applicable regulations in the Code of Federal Regulations, established a framework for the regulation of medical devices intended for human use.

20. Congress established three classes of devices, based on the regulatory requirements needed to provide reasonable assurance of their safety and effectiveness. The three classes of devices are Class I, Class II, and Class III. Class I devices present no unreasonable risk of illness or injury and are subject to regulation through "general controls." 21 U.S.C. 360c(a)(1)(A). Class II devices are potentially more harmful and are subject to general controls, but FDA in addition has authority to require that such devices comply with other "special controls" or performance standards. 21 U.S.C. 360c(a)(1)(B). Class III devices present "a potential unreasonable risk of illness or injury." 21 U.S.C. 360c(a)(1)(C)(ii)(II).

21. Examples of Class I devices include bandages and enema kits. Examples of Class II devices include condoms, some pregnancy test kits and powered wheelchairs. Examples of Class III devices include pacemakers and breast implants.

22. In drafting the 1976 amendments, Congress divided medical devices in two different ways: (1) according to three classes noted above — class I, II, or III, and (2) according to seven basic categories — pre-amendment, post-amendment, substantially equivalent, implant, custom, investigational, and transitional. The current regulatory scheme involved weaving these two methods of subdivision into a workable statutory framework.

23. New devices, including any devices that were not in commercial distribution prior to May 28, 1976, generally referred to as post-amendments devices, are classified automatically

by statute (section 513(f) of the Act (21 U.S.C. 360c(f)) into class III without any FDA rulemaking process. Those devices remain in class III and require a manufacturer to submit to FDA a premarket approval application, unless or until: (1) the device is reclassified into class I or II; (2) FDA issues an order classifying the device into class I or II in accordance with section 513(f)(2) of the Act (21 U.S.C. 360c(f)(2)); or (3) FDA issues an order finding the device to be substantially equivalent, under section 513(i) of the Act (21 U.S.C. 360c(i)), to a predicate device that does not require premarket approval.

24. Before a Class III device may be introduced into the market, a manufacturer must obtain a "premarket approval" ("PMA" may refer to either premarket approval or premarket application) from FDA. 21 U.S.C. 360c(a)(1)(C), 360e(a). To obtain a PMA, the manufacturer must submit information to FDA in a premarket approval application that provides reasonable assurance that the device is safe and effective for its intended use. 21 U.S.C. 360c(a)(1)(C), 360e(a), (c), and (d); 21 C.F.R. §§ 814.

25. PMA is the most detailed type of device marketing application and review required by FDA. The applicant must receive FDA approval of its PMA application prior to marketing the device. PMA approval is based on a determination by FDA that the PMA contains sufficient valid scientific evidence to assure that the device is safe and effective for its intended use(s). PMA requires clinical testing to assure safety and effectiveness.

26. However, devices that were in commercial distribution before May 28, 1976 (the date of enactment of the 1976 amendments), generally referred to as pre-amendments devices, are classified after FDA has: (1) received a recommendation from a device classification panel (an FDA advisory committee); (2) published the panel's recommendation for comment, along with a proposed regulation classifying the device; and (3) published a final regulation classifying the device.

27. A loophole known as the "grandfathering" provision permits Class III devices that were on the market before the 1976 Medical Device Amendment's enactment to remain on the market until FDA initiates and completes a rulemaking requiring the submission of a PMA. 21

U.S.C. 360e(b)(1)(A). In addition, Congress created another loophole which permits new manufacturers to distribute similar devices by showing through a premarket notification process that their new devices are "substantially equivalent" to grandfathered devices. 21 U.S.C. 360e(b)(1)(B). This premarket notification process is known as the "Section 510(k) process," referring to the applicable section of the Act (21 U.S.C. 360(k)). A device is "substantially equivalent" to a grandfathered device only if, among other things, the device has the same "intended use" as the predicate device. 21 U.S.C. 360c(i)(1)(A).

28. It is this grandfathering *loophole* that has allowed the MECTA SpECTrum ECT device onto the market. Specifically, because various ECT machines had been on the market prior to the 1976 enactments of the Medical Device Amendments, MECTA was able to obtain grandfathering clearance for its ECT device without submitting a premarket approval application (PMA) and without having to submit *any* clinical trials concerning the safety and efficacy of its ECT device.

29. Notably, in September 1979, the FDA issued a Rule classifying ECT machines as Class III devices and requiring all manufacturers of ECT devices to submit a PMA application that includes information concerning safety and effectiveness tests for the devices. *See* 44 Fed.Reg. 172, Sept. 4, 1979, pages 51776-77. However, after pressure from the American Psychiatric Association and in light of the fact that not a single ECT manufacturer submitted the requested PMA, the FDA chose not to enforce its Rule/Order.

30. Thereafter, beginning in 1984, the FDA allowed new ECT manufacturers, including MECTA, to simply submit a 510(k) notification (which does not require showing of safety or effectiveness nor does it require presentation of any clinical trial data) to obtain clearance to sell its ECT device.[1]

[1] The distinction between PMA approval and 510(k) clearance is significant. The Supreme Court has noted, the PMA approval process usually takes the FDA 1200 hours to complete, whereas the 510(k) review is completed by the FDA in an average of only 20 hours. Moreover, the 510(k) notification process "requires little information, rarely elicits a negative response from the FDA and gets processed very quickly." *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 478 (1996).

31. Between the late 1970s and the time Plaintiff received their last ECT treatments, the FDA had oscillated numerous times as to what classification should apply to ECT machines and unfortunately never enforced any of its Rules requiring PMA approval for ECT machines. This has resulted in the ECT machines currently on the market, including MECTA's SpECTrum ECT Device, never being subjected to a full FDA PMA review, MECTA has never conducted a clinical trial to demonstrate the safety and efficacy of the SpECTrum device (or any other ECT device) and MECTA has never submitted clinical trials to demonstrate the safety and effectiveness of the SpECTrum ECT device.

32. Contrary to MECTA's false representations, during the relevant time period and presently, the FDA's position has been that "long-term safety and effectiveness of ECT treatment *has not been demonstrated.*" (Emphasis added.) Moreover, as previously mentioned, to date MECTA has not undertaken a single clinical trial to test the safety and efficacy of its ECT device. Nonetheless, during the relevant time period and to this date, MECTA in order to facilitate sales and in order to encourage medical professionals to recommend ECT treatment and in order to convince patients to undergo ECT treatment, states on its website and promotional literature that "MECTA ECT devices bring patients back. Back from debilitating illness, back to their families and friends, back to the life they were meant to live … ECT continues to be the only neuromodulation modality providing up to an 80% response rate … The safety of these [MECTA] devices is unparalleled" and "MECTA has extensive regulatory agency approvals worldwide: U.S. (UL) …" – knowing full well that its promotional statements are false and misleading as there is no support nor clinical trials supporting such an endorsement of safety and efficacy of its ECT device.

33. According to a 2006 analysis of all ECT studies meeting the criteria for the highest and most conclusive level of evidence in medicine: randomized, prospective, double-blind placebo-controlled trials of ECT (conducted by others, not by ECT manufacturers), which compared real ECT with "sham" ECT, "provide definitive evidence that real ECT is no more effective than sham ECT."

C. Defendant MECTA's Failure to Adequately Test, Investigate, Report and Study the Safety and Efficacy of Its ECT Device

34. MECTA has *never* performed any studies or tests to analyze the long-term side effects associated with ECT.

35. Furthermore, MECTA has failed to comply with its pharmacovigilance requirements and mandatory duty of timely investigating, evaluating and reporting adverse events to the FDA. Under the applicable federal regulations, MECTA, as a device manufacturer, had an affirmative responsibility to timely report to the FDA any serious injury that the manufacturer becomes aware of, *from any source* (including as way of example case reports published in scientific articles or other literature), that suggests the manufacturer's device may have caused or contributed to serious injury. *See* 21 C.F.R. §§ 803 *et seq*.

36. In addition, as a medical device manufacturer, MECTA had a duty to investigate all complaints of adverse events (from any source) to determine if a report should be submitted to the FDA. *See* 21 C.F.R. §§ 803.17, 803.18 & 820.198. MECTA also failed to undertake any such efforts to investigate serious adverse events (such as brain injury or permanent memory loss) that the company became aware of through the scientific literature or other sources.

37. The adverse event reporting requirements applicable to device manufacturers are essential for the FDA as well as medical professionals to learn of adverse events as well as the potential frequency of adverse events. The medical device adverse reports that are reported by manufacturers and other stakeholders are published by the FDA on its Manufacturer and User Facility Device Experience ("MAUDE") database which is accessible by the medical community and stakeholders.

38. On multiple occasions, beginning in the mid-1990s and through 2009, when the FDA required ECT manufacturers to submit data and information about their respective ECT devices, MECTA failed to submit any information to the FDA concerning reportable safety risks and adverse events notwithstanding the myriad of medical journal publications that discussed adverse events associated with ECT machines, including the SpECTrum device, and

notwithstanding the fact that the FDA had contemporaneously received public comments from medical professionals and the public in response to the same inquiry that included *hundreds* of complaints of cognitive impairment, brain damage and more than 100 complaints of death associated with ECT devices.

39. Since obtaining clearance, in response to each and every one of the thousands of instances in which MECTA became aware of information reasonably suggesting death or serious injury associated with its device, MECTA conducted no investigation and failed to undertake any medical device vigilance duties.

40. As a result of MECTA's conduct in violating statutory requirements and selective withholding and manipulation of the data surrounding ECT devices, failing to warn of known and knowable risks, and failure to comply with the statutory and common law duties under state law running parallel to such requirements, during the relevant time period, the SpECTrum ECT devices were manufactured, sold, distributed and remained in use without adequate testing, without adequate dissemination of reliable information and data as to safety and effectiveness of the ECT device and without adequate warnings concerning serious and significant risks, including but not limited to risks of brain damage, brain injury, neurocognitive impairment, encephalopathy, structural brain changes, permanent cognitive impairment and permanent memory loss.

D. Defendant MECTA Knew, or Should Have Known, About Serious Injuries, Including Brain Injury and Permanent Memory Loss Associated With its ECT Device, Yet MECTA Failed to Issue Timely Warnings and Instead Falsely Downplayed the Risks to Promote Sales

41. Since its inception in 1938, administration of ECT shock treatment has resulted in innumerable adverse events as to make it virtually impossible that any ECT manufacturer could escape the obligations to investigate, report and warn about such adverse events. For example, from the early days of ECT to the present day, various psychiatric experts have documented brain damage correlated with ECT. A vocal "ECT survivor community" has been voicing their objection to the continued use of shock treatment for decades. Moreover, during FDA hearings

between 2009 and 2011 in which the FDA opened a public docket seeking reports of adverse event complaints, ECT patients submitted thousands of adverse event complaints, hundreds of which alleged serious brain injury. MECTA became aware of these adverse event allegations by virtue of participating in those hearings, and therefore the hearings further invoked MECTA's statutory duty to investigate, evaluate, and if necessary independently and more fully report the complaints to the FDA so that they are fully researched and reflected in the MAUDE database. However, there were no manufacturer-submitted adverse event reports in FDA's MAUDE database corresponding to those adverse event allegations reported until approximately December 2017, illustrating MECTA's systematic and intentional failure to investigate and/or report adverse events to the FDA.

42. "The Electroshock Quotationary" was published in 2006.[2] It recounts an 80-year history of serious adverse events including permanent brain damage resulting from ECT shock treatment, as well as the formation of patient advocacy groups united in their continued opposition to ECT shock treatment. Moreover, it references testimony and studies by U.S. psychiatrists, in which the psychiatrists opine that ECT inherently damages the brain. No account of injury resulting from ECT shock treatment referenced in the Electroshock Quotationary were investigated and reported by MECTA.

43. A textbook titled "Preventable Brain Damage" published in 1992 cites different types of studies that have shown brain damage resulting from ECT (including animal studies, human brain autopsy reports, subjective reports long after the administration of ECT and psychological testing in patients with a history of ECT). According to one animal study, significant differences were noted in cats who received ECT, which showed "clearly irreversible changes such as shadow cells and neuronophagia." Psychological testing of patients with a history of ECT treatments showed the "ECT patients were significantly inferior on all three tests" and "the research using psychological tests with patients with history of many ECTS does

[2] LEONARD ROY FRANK, THE ELECTROSHOCK QUOTATIONARY (2006), http://www.endofshock.com/102C_ECT.PDF.

suggest permanent impairment." In conclusion, the author states: "There seems to be little doubt that ECT has, at least in the past, caused permanent brain damage in some patients and has the capacity to continue to do so."

44. Many other studies have suggested or documented reasonably known brain injury resulting from ECT shock treatment. For example, a study in Archives of General Psychiatry documented that cerebral atrophy was significantly more common in those patients who had ever received ECT.[3]

45. A brain scan study confirmed that brain shrinkage was significantly more common in ECT recipients than other mental patients.[4]

46. A study relating MRI scans of patients demonstrated a strong correlation between the number of previous ECT treatments to loss of brain tissue.[5]

47. Another study found that ECT recipients were twice as likely to have a measurable loss of brain tissue in the front area of the brain and a tripling of the incidence of a loss of brain tissue in the back of the brain.[6]

48. Another study documented intra-cranial bleeding resulting from ECT shock treatment administered using current ECT devices.[7]

49. MECTA, however, remained willfully ignorant or otherwise intentionally failed to follow up on or do any investigation of the adverse events in these and other similar published adverse events in an attempt to evade mandatory reporting duties and keep from having to publicly admit awareness that a risk of permanent brain damage is associated with the use of its ECT device.

---

[3] Weinberger et al., *Structural Abnormalities in the Cerebral Cortex of Chronic Schizophrenic Patients*, 36 ARCHIVES GEN. PSYCHIATRY, 935-39 (1979).
[4] Calloway et al., *ECT and Cerebral Atrophy: A CT Study*, 64 ACTA PSYCHIATRICA SCANDINAVICA 442-45 (1981).
[5] Andreasen et al., *MRI of the Brain in Schizophrenia*, 47 ARCHIVES GEN. PSYCHIATRY, 35-41 (1990).
[6] R.J. Dolan et al., *The Cerebral Appearance in Depressed Subjects*, 16 PSYCHOL. MED., 775-79 (1986).
[7] Kulkarni & Melkundi, *Subdural Hematoma: An Adverse Event of Electroconvulsive Therapy – Case Report and Literature Review*, CASE REPORTS IN PSYCHIATRY (2012).

50. MECTA as a leading manufacturer and distributor of ECT devices, knew and certainly should have known about the potential risks of brain injury, permanent cognitive impairment and permanent memory loss associated with its SpECTrum ECT Device. In addition to the various scientific journal articles, meta-analysis and case reports addressed *supra*, which raised these risk concerns, scientists testified in governmental proceedings concerning these brain injury risks and their mechanism of action. As way of example, Peter Sterling, Ph.D., a neuroscientist and professor at the University of Pennsylvania and ECT researcher, testified before the New York State Assembly on July 18, 2001 regarding the effects of ECT on the brain, and in his testimony to the New York Assembly he stated:

> ECT unquestionably damages the brain, and there are a variety of mechanisms that lead to this damage. In the first place, the electroshock delivered to the skull is basically similar to what you would get out of an electrical wall outlet, except that there is a transformer in the ECT machine that steps up the voltage…when this is done two or three times a week for weeks, it's just completely obvious that this is going to eventually cause some kind of brain damage…
>
> Now the second point, source of brain damage for ECT is that it causes…grand mal epileptic seizures…and this causes an acute rise in blood pressure, well into the hypertensive range…And it frequently causes small…hemorrhages in the brain. And wherever a hemorrhage occurs in the brain, nerve cells die, and they are not replaced. And so one can accumulate these hemorrhages over a period of treatments leading to brain damage.
>
> A third thing that ECT does is to rupture the blood brain barrier. This barrier normally protects the brain from potentially damaging substances in the blood….breaching this barrier exposes nerve cells in the brain to chemical insults that can kill them…also leads…to swelling of the brain…swelling leads to local arrest of blood supply, to loss of oxygen…and to death of neurons.
>
> The fourth thing…is that ECT…causes neurons to release large quantities of …glutamate. Glutamate excites further neuronal activity…and this becomes a vicious cycle…Neurons literally…kill themselves from over activity….the key manifestation of this brain damage is retrograde memory loss….

51. Dr. Sterling's testimony was given during hearings by the New York Assembly which was considering introducing regulations concerning the use, assurance of informed consent and oversight of ECT procedures. As the manufacturer of one of the two main ECT devices in the nation, MECTA either knew or certainly should have known about the Assembly

hearings, the proposed legislation as well as the opinions and medical testimony publicly delivered to the Assembly, including the above opinions and testimony of Dr. Sterling which were directly quoted and referenced in the State Assembly's subsequent March 2002 Report on Electroconvulsive Therapy. MECTA, however, as with its lack of response to the myriad of other previous articles and scientific publications raising concerns about the use of ECT and brain injury, did not undertake any efforts to enhance its device warnings.

52. The true electrical current exposure and eventual brain damage risks ECT patients endure is perhaps best encapsulated by Kenneth Castleman, Ph.D., a Biomedical Engineer and former faculty member and Visiting Committee Chairman of the Department of Electrical and Computer Engineering at Caltech, who issued a report in a previous ECT litigation involving allegations of brain injury. In his report, Dr. Castleman went through the electrical currents an ECT patient receives and summarized it as follows:

> So, to put this all in perspective, the amount of electric current that an ECT machine puts through a patient's head is about 200 times what is considered dangerous for ground fault leakage, approximately 100 times what Tasers, cattle prods, and electric fences use, about the same as what is used for stunning pigs, and roughly one-fifth as much as the electric chair. In addition, the amount of voltage applied to the head (460 volts) is about 400 times what is required to damage a single brain cell. Clearly this amount of electricity has the potential to cause injury to the brain.

53. Notwithstanding the above alleged facts, during all times relevant to this action, MECTA never issued adequate warnings about the risk of brain injury, permanent cognitive injuries and permanent memory loss associated with the ECT SpECTrum Device.

54. Had MECTA issued warnings to medical providers concerning the risk of brain injury, permanent cognitive impairment and permanent memory loss as well as the other serious adverse events associated with the ECT SpECTrum Device, medical providers, including Plaintiff's medical providers, would have heeded these warnings and as is their fiduciary responsibility, would have passed on those warnings to patients, including Plaintiff, during the informed consent process. However, as a result of MECTA's negligent, reckless and fraudulent conduct, and failure to issue adequate warnings, MECTA denied patients, including Plaintiff, the

ability to make truly informed consent.

55. In lieu of issuing appropriate warnings concerning the documented risks associated with ECT, including but not limited to brain damage, permanent cognitive impairment and permanent memory loss, MECTA instead provides a video, books and other literature to give to ECT patients which downplayed side effects, falsely stated that ECT does not cause brain injury, falsely stated that any memory loss issues are temporary and not permanent, falsely claimed that ECT actually improved memory and to further downplay the risks of ECT. Instead, the Video and other literature pinned cognitive adverse events to the patients' underlying condition, other medications and aging.

PLAINTIFF-SPECIFIC ALLEGATIONS

56. Plaintiff, Jon Whitsitt, a police officer, underwent approximately nine sessions of ECT from approximately May 11, 2018 to June 22, 2018, with an ECT device manufactured and/or distributed by Defendant, MECTA. The ECT treatments were prescribed and administered by medical professionals at Raymond G. Murphy Department of Veterans Affairs Medical Center in Albuquerque, New Mexico.

57. Plaintiff's treating psychiatrists and physicians, apparently unaware of ECT's risks of brain injury and permanent neurocognitive side effects (because Defendant had not issued such warnings and instead overtly denied that such risks exist), did not provide Plaintiff with warnings concerning the risk of permanent memory loss, brain injury, or neurocognitive injury. Nor did Plaintiff receive warnings about the risks outlined herein and which Defendant knew of but failed to warn about, including for example, the fact that the safety and efficacy of ECT for long term use had never been tested, the fact that ECT presents a material risk of causing brain trauma, including cell death, in a way that wholly debilitates the patient with permanent cognitive impairment, such that many patients cannot live normal lives after receiving ECT as well as the various other serious injuries outlined in this Complaint.

58. Had Plaintiff been warned concerning the risk of brain injury, memory loss, and permanent neurocognitive decline, he would never have consented to ECT treatment.

59. ECT did not generate improvement in Plaintiff's symptoms. Instead, Plaintiff's memory and cognitive abilities became so impaired that he was required to transfer to an administrative position at the police department where he now performs duties that do not require him to interact with the public and make quick and accurate decisions because, after ECT, his reaction time is delayed, and he can no longer function the way he could prior to ECT.

60. As a result of Mecta's ECT device, Plaintiff sustained numerous injuries, including but not limited to: permanent memory loss; neurocognitive injuries; impaired visual and verbal memory; significant decline in his ability to learn and recall information; a disruption and decline in his ability to encode new information, loss of executive function, and additional physical and psychological harms. In sum, as a result of his repeated exposure to electricity from ECT treatment with Defendant's device, Plaintiff has sustained brain damage, neurocognitive injuries, and permanent memory loss, in addition to other physical, physiological, psychological and emotional injuries and harms.

FIRST CLAIM FOR RELIEF

NEGLIGENCE

AGAINST MECTA AND DOES 1-10

61. Plaintiff repeats, incorporates, and alleges each prior and subsequent allegation as if fully set forth herein.

62. At all relevant times, MECTA owed a duty to Plaintiff and the general public to use reasonable care in researching, manufacturing, designing, analyzing, testing, selling, advertising, promoting, distributing, labeling and marketing of its ECT devices, including the SpECTrum ECT device.

63. Notwithstanding said duty of care, MECTA, individually, as well as through its agents, servants, or employees, negligently, recklessly and carelessly:

i. Failed to provide adequate warnings to the medical community and the public, including Plaintiff and Plaintiff's treating providers at Raymond G. Murphy VA Medical Center, about risks, dangers and side effects associated with the use of its

ECT device, including but not limited to failing to warn about the risks of permanent brain damage, brain injury, permanent neurocognitive injury and permanent memory loss.

ii. Failed to adequately research, test and analyze the safety of its ECT device.

iii. Failed to adequately investigate the reports of serious adverse events, including but not limited to permanent memory loss, neurocognitive decline, death, and brain injury that it knew about or should have known about.

iv. Failed to adequately report adverse events to the FDA.

v. Failed to comply with applicable federal laws and regulations governing medical device manufacturers, including but not limited to, The Federal Food, Drug, and Cosmetic Act (hereinafter, the "Act") (21 U.S.C. 301 *et seq*.), as amended by the Medical Device Amendments of 1976 (the "1976 amendments") (Public Law 94-295), the Safe Medical Devices Act of 1990 (the "SMDA") (Public Law 101-629), the Food and Drug Administration Modernization Act of 1997 ("FDAMA") (Public Law 105-115), the Medical Device User Fee and Modernization Act ("MDUFA") (Public Law 107-250) and the medical device provisions of the Food and Drug Administration Amendments Act of 2007 ("FDAAA") (Public Law 110-85), along with the applicable regulations in the Code of Federal Regulations, including more specifically, but not limited to: 21 C.F.R. §§ 803.1 -803.23; 21 C.F.R. §§ 803.50-803.58; 21 C.F.R. § 820.198; and 21 C.F.R. §807.20.

vi. Failed to inform and warn the medical community, patients and the public that the safety and efficacy of the use, in particular long-term safety and effectiveness of ECT treatment, has never been demonstrated.

vii. Falsely assured the medical community, patients and the public that ECT is safe and effective when it knew or should have known that such a proclamation and assurance of safety and efficacy had never been demonstrated, nor are there double-blind controlled clinical trials to support the veracity of such a statement

for the SpECTrum ECT Device.

viii. Designed, marketed, sold, and distributed its SpECTrum ECT device that carried an unreasonable risk of injury when used as intended by its ordinary consumers, whereas a reasonably prudent manufacturer would conclude that the scientifically perceived danger, at all relevant times, outweighed the benefit of the way the product was so designed and marketed.

64. As a direct and proximate result of one or more of these aforementioned acts or omissions of MECTA, as well as the other acts or omissions of MECTA outlined throughout this Complaint, Plaintiff sustained personal injuries and damages of a personal and pecuniary nature, including past and future medical expenses; past and future lost earnings, earning capacity and profits; past and future pain, suffering, disability and loss of a normal life. These losses are permanent.

WHEREFORE, Plaintiff requests that judgment be entered in his favor and against MECTA for all legally appropriate damages in an amount to be determined at trial, and such additional amounts as the jury and/or the Court shall deem proper, along with costs and all other relief the Court determines just and proper.

SECOND CLAIM FOR RELIEF

STRICT LIABILITY – FAILURE TO WARN

AGAINST MECTA AND DOES 1-10

65. Plaintiff repeats, incorporates, and alleges each prior and subsequent allegation as if fully set forth herein.

66. At the time the SpECTrum ECT Device (used during Plaintiff's ECT treatment between May 11, 2018 and June 22, 2018), left the control of MECTA, it was defective and unreasonably dangerous when designed, labeled, promoted and instructed by MECTA, which is strictly liable for the injuries caused from its use.

67. MECTA failed to provide adequate warnings to the medical community and the public, including Plaintiff and Plaintiff's treating providers at Raymond G. Murphy VA Medical

Center, about risks, dangers and side effects associated with the use of its SpECTrum ECT device, including but not limited to failing to warn about the risks of permanent brain injury, neurocognitive injury, and permanent memory loss.

68. The SpECTrum ECT Device was defective and unreasonably dangerous when it left the possession of Defendants in that there was an absence of warnings alerting the medical community and the public, including Plaintiff and Plaintiff's treating providers at Raymond G. Murphy VA Medical Center, about the dangerous risks associate with the SpECTrum Devices when used for their intended and reasonably foreseeable purpose.

69. The risks attendant to the SpECTrum ECT Device when used for its intended and reasonably foreseeable purpose, include but are not limited to permanent brain injury, neurocognitive injury, and permanent memory loss.

70. At all times relevant hereto, Plaintiff and Plaintiff's healthcare providers used the SpECTrum ECT Device for its intended or reasonably foreseeable purpose.

71. Plaintiff and Plaintiff's healthcare providers reasonably assumed that MECTA had performed adequate testing on its device and had proper policies and procedures in place for investigating adverse events associated with its device, and that Mecta would have provided healthcare providers with sufficient warnings and information to make informed medical decisions for patients.

72. MECTA knew or should have known, by the use of scientific knowledge available, before, at, and after the time of the manufacture, distribution, and sale of the SpECTrum device, of potential risks and side effects associated with the SpECTrum device.

73. The warnings and instructions provided with the SpECTrum device did not adequately warn of the potential risks and side effects.

74. MECTA had a continuing duty to warn the medical community and public, including Plaintiff and Plaintiff's healthcare providers, of the potential risks associated with the SpECTrum device.

\\

75. MECTA, knowing that said product when used as intended and promoted was defective and dangerous, acted in a despicable manner and in conscious disregard of the safety of the public, including Plaintiff, when it placed the product in the stream of commerce without warning of the defects, and knew when so placed that it would be used without inspection for defects when so used.

76. As a direct and proximate result of MECTA's failure to adequately warn, as well as the other acts or omissions of MECTA outlined throughout this Complaint, Plaintiff sustained personal injuries and damages of a personal and pecuniary nature, including past and future medical expenses; past and future lost earnings, earning capacity and profits; past and future pain, suffering, disability and loss of a normal life. These losses are permanent.

WHEREFORE, Plaintiff requests that judgment be entered in his favor and against MECTA for all legally appropriate damages in an amount to be determined at trial, and such additional amounts as the jury and/or the Court shall deem proper, along with costs and all other relief the Court determines just and proper.

THIRD CLAIM FOR RELIEF

STRICT LIABILITY – DESIGN DEFECT

AGAINST MECTA AND DOES 1-10

77. Plaintiff repeats, incorporates, and alleges each prior and subsequent allegation as if fully set forth herein.

78. At the time the SpECTrum ECT Device (used during Plaintiff's ECT treatment between May 11, 2018 and June 22, 2018), left the control of MECTA, it was defective and unreasonably dangerous when manufactured and designed by MECTA, who is strictly liable for the injuries caused from its use.

79. At all times relevant hereto, the SpECTrum device was expected to, and did reach prescribing physicians and consumers, including Plaintiff and Plaintiff's healthcare providers, without a substantial change in the condition in which it was sold.

\\

80. At all times relevant hereto, Plaintiff and Plaintiff's healthcare providers used the SpECTrum device for its intended or reasonably foreseeable purpose as provided by MECTA.

81. At all times relevant hereto, the SpECTrum device was dangerous, unsafe, and defective in design including but not limited to the risks of permanent brain injury, permanent neurocognitive injury, and permanent memory loss associated with ECT treatment with the SpECTrum device.

82. MECTA knew or should have known, by the use of scientific knowledge available, before, at, and after the time of the manufacture, distribution, and sale of the SpECTrum device, of potential risks and side effects associated with the SpECTrum device.

83. The risks attendant to the SpECTrum ECT Devices as designed, manufactured, promoted, and sold by MECTA greatly outweighed any possible benefits to be expected.

84. MECTA knew that the SpECTrum ECT Device manufactured, designed, labeled, promoted and/or sold by it, when used as promoted and instructed by MECTA, was defective and dangerous in the manner described throughout this complaint. Specifically, the true electrical current exposure that ECT patients endure when receiving treatment with an ECT device is about 200 times what is considered dangerous for ground fault leakage, approximately 100 times what Tasers, cattle prods, and electric fences use, and roughly one-fifth as much as the electric chair. In addition, the amount of voltage applied to the head (460 volts) is about 400 times what is required to damage a single brain cell. This amount of electricity has the potential to cause injury to the brain.

85. MECTA knew that, because said use was unreasonably dangerous and defective, SpECTrum ECT Devices could not be safely used for the purposes intended and promoted.

86. MECTA, knowing that said product when used as intended and promoted was defective and dangerous, acted in a despicable manner and in conscious disregard of the safety of the public, including Plaintiff, when it placed the product in the stream of commerce without warning of the defects, and knew when so placed that it would be used without inspection for defects when so used.

87. As a direct and proximate result of MECTA's dangerous design and failure to adequately test, as well as the other acts or omissions of MECTA outlined throughout this Complaint, Plaintiff sustained personal injuries and damages of a personal and pecuniary nature, including past and future medical expenses; past and future lost earnings, earning capacity and profits; past and future pain, suffering, disability and loss of a normal life. These losses are permanent.

WHEREFORE, Plaintiff requests that judgment be entered in his favor and against MECTA for all legally appropriate damages in an amount to be determined at trial, and such additional amounts as the jury and/or the Court shall deem proper, along with costs and all other relief the Court determines just and proper.

FOURTH CLAIM FOR RELIEF

BREACH OF IMPLIED WARRANTY OF MERCHANTABILITY

AGAINST MECTA AND DOES 1-10

88. Plaintiff repeats, incorporates, and alleges each prior and subsequent allegation as if fully set forth herein.

89. At all times relevant, MECTA was a manufacturer and seller of ECT medical devices.

90. MECTA sold the subject ECT Device: the "SpECTrum" ECT Device.

91. The SpECTrum ECT Device MECTA manufactured, distributed and sold, and which was used during Plaintiff's ECT procedures, was not merchantable at the time of sale.

92. As a direct and proximate result of one or more of these aforementioned acts or omissions of MECTA, as well as the other acts or omissions of MECTA outlined throughout this Complaint, Plaintiff sustained personal injuries and damages of a personal and pecuniary nature, including past and future medical expenses; past and future lost earnings, earning capacity and profits; past and future pain, suffering, disability and loss of a normal life. These losses are permanent.

\\

WHEREFORE, Plaintiff requests that judgment be entered in his favor and against MECTA for all legally appropriate damages in an amount to be determined at trial, and such additional amounts as the jury and/or the Court shall deem proper, along with costs and all other relief the Court determines just and proper.

FIFTH CLAIM FOR RELIEF

BREACH OF IMPLIED WARRANTY OF FITNESS FOR A PARTICULAR PURPOSE

AGAINST MECTA AND DOES 1-10

93. Plaintiff repeats, incorporates, and alleges each prior and subsequent allegation as if fully set forth herein.

94. At all times relevant, MECTA was a manufacturer and seller of the SpECTrum ECT Devices.

95. Prior to the time of sale, MECTA had reason to know that medical providers, including but not limited to Plaintiff's medical providers, would use MECTA's SpECTrum ECT Devices on their respective patients, including but not limited to Plaintiff.

96. Patients such as Plaintiff and medical providers rely upon MECTA as the designer, manufacturer, distributor and/or promoter of the SpECTrum ECT Devices, to design, manufacture, label and distribute medical devices that are safe and effective for the intended and/or promoted use.

97. In consideration, as part of the sale of the SpECTrum ECT Devices, an implied warranty arose that the subject devices would be safe and suitable for the intended and promoted use.

98. In breach of this implied warranty of fitness for a particular purpose, the SpECTrum ECT Devices, were not delivered as warranted because they were not safe or effective for the intended and promoted use.

99. As a direct and proximate result of one or more of these aforementioned acts or omissions of MECTA, as well as the other acts or omissions of MECTA outlined throughout this

Complaint, Plaintiff sustained personal injuries and damages of a personal and pecuniary nature, including past and future medical expenses; past and future lost earnings, earning capacity and profits; past and future pain, suffering, disability and loss of a normal life. These losses are permanent.

WHEREFORE, Plaintiff requests that judgment be entered in his favor and against MECTA for all legally appropriate damages in an amount to be determined at trial, and such additional amounts as the jury and/or the Court shall deem proper, along with costs and all other relief the Court determines just and proper.

SIXTH CLAIM FOR RELIEF

BREACH OF EXPRESS WARRANTY

AGAINST MECTA AND DOES 1-10

100. Plaintiff repeats, incorporates, and alleges each prior and subsequent allegation as if fully set forth herein.

101. At all times relevant, MECTA was the manufacturer, distributor, promoter and seller of the SpECTrum ECT Device.

102. MECTA expressly warranted to the public and the medical community, including Plaintiff's treating physicians and psychiatrists, that its SpECTrum ECT Device was safe and effective; that its SpECTrum ECT Device did not cause brain injury; that its SpECTrum ECT Device did not cause permanent memory loss; that its SpECTrum ECT Device did not cause long-term or persistent effects on intellectual abilities or memories; and other similar warranties of safety and efficacy.

103. The aforementioned representations, individually and collectively, were part of the basis of the bargain between Plaintiff (including their medical providers) and MECTA.

104. Plaintiff (including the medical community and their medical providers) directly and indirectly relied on the aforementioned representations by MECTA.

105. MECTA's aforementioned representations and warranties were false.

\\

106. In breach of MECTA's express warranties and representations, there in reality are no clinical trials or any other reliable evidence demonstrating that ECT treatment or treatment with the SpECTrum ECT device is the safest and most effective treatment for depression. Contrary to MECTA's warranties, ECT treatment and its SpECTrum ECT Device, can and does cause brain injury. Contrary to MECTA's warranties, ECT treatment and its SpECTrum ECT Device, can and does cause permanent memory loss. Contrary to MECTA's warranties, ECT treatment and its SpECTrum ECT Device, can and does cause long-term and persistent effects on intellectual abilities or memories. And, contrary to MECTA's warranties, the truth is that the long-term efficacy and safety of ECT treatment has *never* been demonstrated.

107. As a direct and proximate result of one or more of these aforementioned acts or omissions of MECTA, as well as the other acts or omissions of MECTA outlined throughout this Complaint, Plaintiff sustained personal injuries and damages of a personal and pecuniary nature, including past and future medical expenses; past and future lost earnings, earning capacity and profits; past and future pain, suffering, disability and loss of a normal life. These losses are permanent.

WHEREFORE, Plaintiff requests that judgment be entered in his favor and against MECTA for all legally appropriate damages in an amount to be determined at trial, and such additional amounts as the jury and/or the Court shall deem proper, along with costs and all other relief the Court determines just and proper.

SEVENTH CLAIM FOR RELIEF

FRAUD, WILLFUL AND WANTON CONDUCT

AGAINST MECTA AND DOES 1-10

108. Plaintiff repeats, incorporates, and alleges each prior and subsequent allegation as if fully set forth herein.

109. As a medical device company, MECTA had an affirmative duty to warn regarding all risks it knew, learned or should have known about, associated with its medical devices, including but not limited, its SpECTrum ECT Device.

110. MECTA intentionally concealed adverse event information, and intentionally provided misleading and inaccurate information that was material to medical providers and patients, which misled medical providers and patients, including Plaintiff and his medical providers, who were relying directly and/or indirectly upon MECTA's representations and concealment.

111. MECTA's propagation of false and misleading information concerning the safety and efficacy of its SpECTrum ECT devices as well as intentional failure and refusal to properly test, study, report and investigate adverse events associated with its SpECTrum ECT devices caused healthcare providers, patients, and the general public, including Plaintiff, to be misled about the risks and benefits of ECT therapy and the SpECTrum ECT devices.

112. In addition to concealing and not reporting adverse events and risks, MECTA made intentional affirmative misrepresentations to the public, patients, and the medical community, including Plaintiff's medical providers, that its SpECTrum ECT Device was safe and effective; that its SpECTrum ECT Device did not cause brain injury; that its SpECTrum ECT Device did not cause permanent memory loss; that its SpECTrum ECT Device did not cause any long-term or persistent effects on intellectual abilities or memories; and other similar assurances of safety and efficacy.

113. Specifically, MECTA provided an instructional manual to each purchaser of its machine, which included statements such as "memory deficits diminish rapidly after termination of the course of ECT" and standardized tests indicate that "probably by one month and certainly by six months post-ECT, performance on objective memory testing is at least back to baseline." For patients with persistent deficits in objective memory, MECTA's manual suggests that this is the patient's mental illness, not the result of ECT. The manual also assured recipients that "electrical stimulation is not sufficient to cause neuronal damage" and is "clearly not of the severity to lead to significant cerebral metabolic derangements."

114. One of the books MECTA promoted to educate the public and medical professionals included a Q & A, which stated, inter alia:

- "What are the bad effects of ECT?" – "Memory loss is the biggest fear of many entering ECT. Excellent, objective, studies show no permanent memory loss after ECT, nor any impairment of one's ability to remember. Some minor events which occur just before ECT may be lost in memory, but most ECT patients recall everything quite clearly."
- "How safe is ECT?" – "Studies show ECT is actually safer than getting a tooth pulled or driving on a freeway, and certainly safer than almost all psychiatric and most general medications. However, for anyone to have ECT, he must sign a permission form. This form lists all manner of dreadful complications, such as broken bones, heart arrythmias, and even death. In fact, none of these has happened in this institution, and most of these have not occurred anywhere in many years. The form must list these possibilities as required by law, but these complications stem from the earliest ECT's given many years ago."
- "Does ECT produce brain damage?" – "There is no evidence that ECT damages the brain, even though such damage has been looked for extensively."

115. On information and belief, MECTA provided these materials to Plaintiffs' treating providers, who directly and indirectly relied on the aforementioned representations by MECTA, which Plaintiff, in turn, also relied on.

116. When MECTA made these aforementioned representations and/omissions, it knew these representations and/or omissions were false or willfully and/or wantonly and recklessly disregarded whether the representations and/or omissions were true. Upon information and belief, these representations and/or omissions were made by MECTA with the intent of defrauding and deceiving the public and the medical community and with the intent of inducing hospitals and doctors to use its SpECTrum ECT Device and/or for patients, such as Plaintiff, to consent to ECT treatment.

117. MECTA made the aforementioned representations and/or omissions with the intention and expectation that they would be relied upon by patients, doctors and the general

public, including Plaintiff.

118. MECTA's aforementioned representations were false and MECTA knew or should have known that they were false. In reality, there are no clinical trials or any other reliable evidence demonstrating that ECT treatment or treatment with the SpECTrum ECT device is the safest and most effective treatment for severe depression. Contrary to MECTA's statements, ECT treatment and its SpECTrum ECT Device, can and does cause brain injury. Contrary to MECTA's representations, ECT treatment and the SpECTrum ECT Device, can and does cause permanent memory loss. Contrary to MECTA's representations, ECT treatment and its SpECTrum ECT Device, can and does cause long-term and persistent effects on intellectual abilities and memories. Contrary to MECTA's representations, the reality is that the long-term efficacy and safety of ECT treatment has *never* been demonstrated.

119. As a result of its aforementioned conduct as well as the conduct outlined throughout this Complaint, MECTA is guilty of willful and wanton conduct which shows an utter indifference to or conscious disregard for the safety of the Plaintiff and others.

120. Had MECTA not made these false representations, omissions and concealments, and had it issued warnings to medical providers concerning the risks of brain injury, permanent cognitive impairment and permanent memory loss as well as the other serious adverse events associated with the ECT SpECTrum Device, as well as the lack of demonstrated long-term safety and efficacy of its device, medical providers, including Plaintiff's medical providers, would have heeded these warnings and as is their fiduciary responsibilities, would have passed on those warnings to patients during the informed consent process. However, as a result of its willful, wanton and fraudulent conduct, MECTA denied patients, including Plaintiff, the ability to make truly informed consent.

121. Had Plaintiff been warned concerning the risk of permanent brain injury or permanent neurocognitive decline and had they been warned about the lack of efficacy and safety for the long-term use of ECT, they would never have consented to ECT treatment.

\\

122. The actions and conduct of MECTA as alleged herein were wanton, grossly negligent and reckless and demonstrated a complete disregard and reckless indifference to the safety and welfare of the Plaintiff in particular and to the public generally in that MECTA did willfully and knowingly falsely promote ECT treatment and its ECT SpECTrum Device with the specific knowledge that its ECT SpECTrum Device would be used without adequate instructions and warnings and without adequate knowledge regarding its efficacy, risk and long-term side effects.

123. The actions and conduct of MECTA as alleged herein was malicious, fraudulent and oppressive toward the Plaintiff in particular and the public generally, and MECTA conducts itself in a willful, wanton and reckless manner.

124. As a direct and proximate result of one or more of these aforementioned acts or omissions of MECTA, as well as the other acts or omissions of MECTA outlined throughout this Complaint, Plaintiff sustained personal injuries and damages of a personal and pecuniary nature, including past and future medical expenses; past and future lost earnings, earning capacity and profits; past and future pain, suffering, disability and loss of a normal life. These losses are permanent.

WHEREFORE, Plaintiff requests that judgment be entered in his favor and against MECTA for all legally appropriate damages in an amount to be determined at trial, and such additional amounts as the jury and/or the Court shall deem proper, along with costs and all other relief the Court determines just and proper.

EIGHTH CLAIM FOR RELIEF

VIOLATION OF NEW MEXICO'S UNFAIR PRACTICES ACT

(NMSA § 57-12-1 *et seq*.)

AGAINST MECTA AND DOES 1-10

125. Plaintiff repeats, incorporates, and alleges each prior and subsequent allegation as if fully set forth herein.

\\

126. There was in force at the time of the sale of MECTA's SpECTrum ECT Devices a statute in the State of New Mexico known as the New Mexico Unfair Practices Act, NMSA § 57-12-1 *et seq*.

127. MECTA is a "person" as defined by the New Mexico Unfair Practices Act.

128. § 57-12-2 of the New Mexico Unfair Practice Act defines "unfair or deceptive acts or practices" to include an act specifically declared unlawful pursuant to the Act or "a false or misleading oral or written statement, visual description or other representation of any kind knowingly made in connection with the sale, lease, rental or loan of goods or services by any person in the regular course of his trade or commerce, which may, tends to or does deceive or mislead any person."

129. At all relevant times, MECTA represented to the general public, the medical community, including Plaintiff's medical providers: that its SpECTrum ECT Device is safe and effective for treating depression; that its SpECTrum ECT Device does not cause brain injury; that its SpECTrum ECT Device does not cause permanent memory loss; that its SpECTrum ECT Device does not cause any long-term or persistent effects on intellectual abilities or memories; that MECTA has "extensive regulatory approvals worldwide[,]" including in the U.S.; that ECT provides "up to an 80% response rate"; and other similar warranties of safety and efficacy.

130. At all relevant times, MECTA provided an instructional manual to each purchaser of its machine, which included statements such as "memory deficits diminish rapidly after termination of the course of ECT" and standardized tests indicate that "probably by one month and certainly by six months post-ECT, performance on objective memory testing is at least back to baseline." For patients with persistent deficits in objective memory, MECTA's manual suggests that this is the patient's mental illness, not the result of ECT. The manual also assured recipients that "electrical stimulation is not sufficient to cause neuronal damage" and is "clearly not of the severity to lead to significant cerebral metabolic derangements."

131. One of the books MECTA promoted to educate the public and medical professionals included a Q & A, which stated, inter alia:

a. "What are the bad effects of ECT?" – "Memory loss is the biggest fear of many entering ECT. Excellent, objective, studies show no permanent memory loss after ECT, nor any impairment of one's ability to remember. Some minor events which occur just before ECT may be lost in memory, but most ECT patients recall everything quite clearly."

b. "How safe is ECT?" – "Studies show ECT is actually safer than getting a tooth pulled or driving on a freeway, and certainly safer than almost all psychiatric and most general medications. However, for anyone to have ECT, he must sign a permission form. This form lists all manner of dreadful complications, such as broken bones, heart arrythmias, and even death. In fact, none of these has happened in this institution, and most of these have not occurred anywhere in many years. The form must list these possibilities as required by law, but these complications stem from the earliest ECT's given many years ago."

c. "Does ECT produce brain damage?" – "There is no evidence that ECT damages the brain, even though such damage has been looked for extensively."

132. At all relevant times, MECTA used exaggeration, innuendo, or ambiguity as to a material fact which misled the medical community, Plaintiff's medical providers (and, in turn, Plaintiff), to believe that its ECT device was safe and effective.

133. MECTA willfully engaged in making the aforementioned false and misleading misrepresentations, with intent that others rely upon the concealment, suppression or omission of such material fact, in connection with the sale of its SpECTrum ECT devices, during the regular course of Mecta's trade or commerce.

134. Accordingly, MECTA has violated the New Mexico Unfair Practices Act § 57-12-1 *et seq*.

135. As a direct and proximate result of one or more of these aforementioned acts or omissions of MECTA, as well as the other acts or omissions of MECTA outlined throughout this Complaint, Plaintiff sustained personal injuries and damages of a personal and pecuniary nature,

including past and future medical expenses; past and future lost earnings, earning capacity and profits; past and future pain, suffering, disability and loss of a normal life. These losses are permanent.

136. Plaintiff is also entitled to attorneys' fees and treble damages as a result of MECTA's violations of the New Mexico Unfair Practices Act.

WHEREFORE, Plaintiff requests that judgment be entered in his favor and against MECTA for all legally appropriate damages in an amount to be determined at trial, and such additional amounts as the jury and/or the Court shall deem proper, along with costs and all other relief the Court determines just and proper.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff demands judgment against Defendant on all counts of the complaint, and requests compensatory damages, together with interest, cost of suit, attorneys' fees, and all such other relief as the Court deems just and proper as well as:

1. For general damages, in an amount exceeding this Court's jurisdictional minimum and to be proven at the time of trial;
2. For specific damages, in an amount to be proven at the time of trial;
3. For medical, incidental, hospital, psychological care and other expenses, in an amount to be proven at trial;
4. For loss of earnings and earning capacity, in an amount to be proven at the time of trial;
5. For an award of pre- and post-judgment interest, as provided by law;
6. For exemplary or punitive damages, in an amount to be determined at the time of trial;
7. For an award providing for payment of costs of suit and attorneys' fees to Plaintiff, as provided by law;
8. For such other and further relief as this Court deems just and proper.

DEMAND FOR JURY TRIAL

Plaintiff hereby demands a trial by jury as to all issues.

DATED: June 15, 2021

Respectfully submitted,
BAUM HEDLUND ARISTEI & GOLDMAN, P.C.

/s/ Monique Alarcon

Monique Alarcon (CA SBN: 311650)
Bijan Esfandiari (CA SBN: 223216)
BAUM HEDLUND ARISTEI & GOLDMAN, P.C.
10940 Wilshire Blvd., Suite 1600
Los Angeles, CA 90024
Tel: (310) 207-3233 // Fax: (310) 820-7444
malarcon@baumhedlundlaw.com
besfandiari@baumhedulundlaw.com